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10/733,135

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EXAMINER

WORLEY, CATHY KINGDON

ART UNIT

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/733,135
Filing Date: December 11, 2003
Appellant(s): ARNTZEN ET AL.

Janae E. Lehman Bell
For Appellant

SUPPLEMENTAL EXAMINER'S ANSWER

Responsive to the reply brief submitted on May 18, 2009, a supplemental Examiner's Answer is set forth below:

Appellant may file another reply brief in compliance with 37 CFR 41.41 within two months of the date of mailing of this supplemental examiner's answer. Extensions of time under 37 CFR 1.136(a) are not applicable to this two month time period. See 37 CFR 41.43(b)-(c).

A Technology Center Director or designee has approved this supplemental examiner's answer by signing below:

/Michael G. Wityshyn/

Acting Director, Technology Center 1600

In the Reply Brief filed on May 18, 2009, the Appellant states that the references do not provide a reasonable expectation of success that a plant-expressed immunogen would survive digestion in an animal's gut when administered orally and survive at levels that would be able to generate an immune response (see first paragraph on page 6 of the reply brief).

This is not persuasive, however, because Kapikian et al clearly teach that rotavirus antigens are effective when administered orally, therefore, they teach that

these antigens survive digestion and survive at levels that generate an immune response. This provides an expectation of success.

The Appellant states that Kapikian et al is not relevant because Kapikian et al teaches the oral administration of attenuated, whole rotovirus strains used as vaccines, and that these vaccines survive the gut because they are encapsulated in a protective viral particle, and the Appellant argues that this difference makes Kapikian et al not predictive that an immunogen expressed in a plant and administered orally would elicit an immune response (see second paragraph on page 6 of the reply brief).

This is not persuasive, however, because Kapikian et al specifically teach that the viral protein VP7 is the major neutralization protein of a human rotovirus belonging to serotypes 1, 2, or 4 (see right column on page S543). They teach that a hybrid or reassortant rotovirus can be generated via reassortment with a human and a rhesus rotovirus (see paragraph bridging left and right columns on page S543). They propose that this hybrid virus would possess only the major neutralization protein (VP7) of a human rotovirus, and they also suggest VP3 as a potentially neutralizing antigen (see last paragraph on page S543). Kapikian's discussion of reassortant rotoviruses teaches that a hybrid virus can be used that includes only one human rotovirus antigen, such as VP7 or VP3 (see last paragraph on page S543). This suggests that having only one of the neutralizing proteins is sufficient for generating an immune response. Furthermore, because the viral

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particle is not infective, it only serves as a carrier to present the antigen. There is no need for the antigen to be protected in order for it to be effective for generating an immune response in the mucosal membrane.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Cathy K. Worley/
Primary Examiner, Art Unit 1638

Conferees:

/Anne Marie Grunberg/
Supervisory Patent Examiner, Art Unit 1638

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